Administration ("FDA").[1] Medicare does not pay for medical procedures or services performed using devices that have not been approved for marketing by the FDA. In their *qui tam* complaint, Petitioners allege Medtronic falsely certified that its Model 4004/4004M leads were FDA-approved. In reliance on that false certification, Medicare paid over $500 million for medical procedures and services associated with those unapproved leads. Petitioners sued under the FCA to recover that money on behalf of the United States.

Petitioners were the *first* to discover that Medtronic's leads were not FDA-approved. In July 1998, Medtronic had submitted a PMA Supplement Application to the FDA for premarket approval of Model 4004 leads with "platinum sputter" coated wires. Medtronic represented that the "platinum sputter" coating would prevent the leads from failing due to metal ion oxidation ("MIO") – a failure mechanism that had haunted Medtronic's earlier models. The FDA approved Medtronic's PMA Supplement Application "subject to the conditions described" in a "Conditions of Approval" letter that the FDA attached. Those Conditions of Approval stated, in no uncertain terms, that "[b]efore making any change affecting the safety or effectiveness of the device," Medtronic must "submit a PMA supplement for review and approval by [the] FDA." The FDA also gave Medtronic immediate permission to "begin commercial distribution of the [Model 4004 platinum-sputter coated leads]." However, the FDA warned Medtronic that "[f]ailure to comply with the conditions of approval invalidates this approval order."

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[1] A pacemaker lead is essentially a metal wire surrounded by insulation that transmits the electronic pulse from the pacemaker to the heart.

While conducting discovery in a different lawsuit under a court-approved protective order, Petitioners discovered evidence that Medtronic had ignored the FDA's conditions, and, one month after FDA approval, instituted an internal "Engineering Change Order/Request" for the leads. The Engineering Change Order changed the design specification of the platinum sputter. Although this change to the design specification affected the safety and effectiveness of the leads (causing the leads to malfunction), Medtronic never submitted "a PMA supplement for review and approval by [the] FDA," as the Conditions of Approval and the Code of Federal Regulations explicitly required. Nor did Medtronic *publicly* disclose this change. Medtronic did, however, sell the altered leads under the same "Model 4004" name and description, even though, as altered, they were a different product than the one approved by the FDA and one that predictably resulted in tens of thousands of failures after implantation in people's bodies.

Upon learning of this secret design change, Petitioners blew the whistle on Medtronic by filing this *qui tam* lawsuit. Petitioners allege that Medtronic defrauded the Medicare system by failing to disclose that the leads Medtronic sold were different from the ones that had been approved by the FDA, therefore causing Medicare to improperly pay over $500 million for medical claims associated with unapproved medical devices.

Prior to the filing of this suit, neither Medtronic's secret change to its internal platinum sputter design specification nor that change's effect on the Medicare system had ever been publicly disclosed.

B. The False Claims Act's Jurisdictional Bar

In order to separate opportunistic plaintiffs seeking to take advantage of information in the public domain from genuine whistleblowers like Petitioners here, Congress adopted the public disclosure bar of the False Claims Act. That provision says that "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . ." 31 U.S.C. § 3730(e)(4)(A).

The circuits have interpreted the phrase "allegations or transactions" to describe alternate ways in which there can be public disclosure of fraud. The first method of public disclosure is an explicit *allegation* of fraud. The second method is where there have been disclosures of the essential elements of the fraudulent *transaction* such that the allegation of fraud can be inferred. The "essential elements" of a fraudulent transaction are more than just general "information" related to the transaction – they are the actual misrepresented state of facts and the actual true state of facts. *E.g.*, *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 330-32 (6th Cir. 1999); *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 653 (D.C. Cir. 1994). Many circuits use a mathematical formula to describe the inquiry. There can be a *direct* public disclosure of the allegation of fraud ("Z"), or the allegation of fraud (the "Z") can be *inferred* through the disclosure of the "elements" of the fraudulent transaction: the true state of facts ("X") and the misrepresented state of facts ("Y") ("X + Y = Z"). *Jones*, 160 F.3d at 331; *Springfield Terminal*, 14 F.3d at 654.

In order for the jurisdictional bar to apply, a court must also determine that the relator's complaint is "based upon" either the public disclosure of "Z" or the public disclosure of

"X+Y." *United States ex rel. Burns v. A.D. Roe Co., Inc.*, 186 F.3d 717, 725 (6th Cir. 1999); *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1348 (4th Cir. 1994).

C. The Sixth Circuit's Decision

The Sixth Circuit held that Petitioners' *qui tam* lawsuit was jurisdictionally barred under 31 U.S.C. § 3730(e)(4)(A) because it was "based upon" "allegations or transactions" that had been publicly disclosed in various product liability lawsuits previously filed against Medtronic. Those state law tort suits, which alleged that Medtronic designed defective leads and fraudulently misrepresented important safety information to the FDA, were wholly different from Petitioners' federal FCA suit, which alleges that Medtronic defrauded Medicare by selling an unapproved product.

Nevertheless, the Sixth Circuit held that those state law tort suits provided sufficient prior public disclosure of both the "allegation" of fraud at issue in Petitioners' lawsuit ("Z"), Pet. App. 9a-11a, and the essential elements of the fraudulent transaction at issue in Petitioners' lawsuit ("X+Y"), Pet. App. 7a-9a. The Sixth Circuit also held that Petitioners' lawsuit was "based upon" those public disclosures because it was "supported by" those disclosures. Pet. App. 11a. In so holding, the Sixth Circuit added to the growing confusion among the circuits with regard to the meaning of the jurisdictional bar provision.

REASONS FOR GRANTING THE WRIT

This case concerns the FCA's "Public Disclosure Bar" and specifically construction of the statutory phrase "based upon the public disclosure of allegations or transactions." There is an acknowledged circuit split regarding the interpretation of the phrase "based upon" that this Court should resolve. Moreover, this Court has never addressed the interpretation of "allegations or transactions," which has similarly produced inconsistent results in the courts of appeals, and should take this opportunity to visit that question as well. *See Findley*, 105 F.3d at 681 (noting "circuit splits concerning the meaning of the words 'based upon,' 'public disclosure,' [and] 'allegations or transactions'"). The FCA remains the most important tool in the government's fight against government contract abuse, but the Sixth Circuit's decision in this case threatens the continued viability of that tool.

Under the Public Disclosure Bar, a *qui tam* relator's lawsuit is jurisdictionally barred if it is "based upon the public disclosure of allegations or transactions" from various, previous public proceedings. In other words, if the relator's suit is founded, in some manner, on information that was already publicly available (in certain forums), then the suit is barred. What remains unclear is the quantum and type of information that constitutes "allegations or transactions" within the meaning of the bar and to what extent the *qui tam* suit must rely (be "based upon") that information in order for the jurisdictional bar to apply. This case squarely implicates those two questions.

I. THE COURT SHOULD RESOLVE THE CIRCUIT CONFLICT AND CONFUSION OVER THE MEANING OF THE PHRASE "BASED UPON" AS USED IN THE "PUBLIC DISCLOSURE BAR" OF THE FALSE CLAIMS ACT

There is no question that there is a circuit split concerning the degree to which a relator's suit must be "based upon" prior public disclosures. The Sixth Circuit in this case, consistent with several other courts of appeals, altered the phrase "based upon" to the different phrase "supported by," meaning that a *qui tam* relator's suit is jurisdictionally barred if it is merely "supported by" publicly disclosed allegations or transactions. Pet. App. 11a. Other courts of appeals have followed the plain meaning of "based upon" and determined that a False Claims Act action can only be barred if the allegations were "derived from" a public disclosure or where the relator explicitly "relied upon" the public disclosure in bringing his suit. The latter reading is compelled by the plain language of the provision and is consistent with the original reasons behind the enactment of the public disclosure bar.

A. The Circuits Are Split On The Meaning Of "Based Upon"

In this case, the panel found that Petitioners' claims were "based upon" prior disclosures because their complaint was "supported by [the public disclosure]," which "includes any action based even partly upon public disclosures." Pet. App. 11a (quoting *United States ex rel. Jones v. Horizon Healthcare Corp.*, 160 F.3d 326, 332 (6th Cir. 1998)). The Sixth Circuit has previously acknowledged that its reading of the "based upon" element as requiring only that the *qui tam* action be "supported by" the prior public disclosures is at odds with the Fourth Circuit's decision in *United States ex*

rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994). *United States ex rel. McKenzie v. Bellsouth Telecommunications, Inc.*, 123 F.3d 935, 940 (6th Cir. 1997). The Fourth Circuit in *Siller* held that "based upon" means "derived from," a considerably stricter standard that is closer to actual language of the statute. 21 F.3d at 1347-49.

In addition to the Fourth Circuit's opinion in *Siller*, the Seventh Circuit's decision in *United States v. Bank of Farmington*, 166 F.3d 853, 863 (7th Cir. 1999) is similarly in conflict with the Sixth Circuit's legal interpretation of "based upon." After noting the dispute in the Circuits over the meaning of "based upon," the *Bank of Farmington* court concluded that the "Fourth Circuit's interpretation of 'based upon' is the better on the grounds of both plain meaning and public policy." *Id.*

Nevertheless, the Sixth Circuit's weakened formulation finds support in a number of circuits who equat "based upon" with less demanding standards like "similar to" or "supported by," which apply "regardless of where the relator obtained his information." *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1990). These circuits include, in addition to the Second: the Third, *United States ex. rel. Mistick PBT v. Housing Authority of the City of Pittsburgh*, 186 F.3d 376, 394-402 (3d Cir. 1999); the Eighth, *Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1044-47 (8th Cir. 2002); the Ninth, *United States ex rel. Biddle v. Board of Trustees of the Leland Stanford, Jr. Univ.*, 161 F.3d 533, 538 (9th Cir. 1998); the Tenth, *United States ex rel. Fine v. Advanced Sciences, Inc.*, 99 F.3d 1000, 1006 (10th Cir. 1996); Eleventh, *Cooper v. Blue Cross and Blue Shield*, 19 F.3d 562, 567 (11th Cir. 1994); and D.C., *United States ex*

rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 688 (D.C. Cir. 1997).

Several of those opinions, however, have drawn vigorous dissents. *See, e.g.*, *Mistick PBT*, 186 F.3d at 394-402 (3d Cir. 1999) (Becker, J., dissenting from majority's adoption of "supported by" inquiry); *United States ex rel. Fine v. Advance Sciences, Inc.*, 99 F.3d 1000, 1008 (10th Cir. 1996) (Henry, J., questioning the majority's expansive definition of "based upon"). In fact, in the Sixth Circuit's *Jones* decision, Judge Gilman expressed his strong disagreement with the "supported by" formulation, which he thought was an "unnatural contortion of the language to reach a result that is not fairly supported by the statute itself." *Jones*, 160 F.3d at 336 (Gilman, J., concurring). He found persuasive, instead, Judge Luttig's interpretation in *Siller*, which Judge Gilman described as "both linguistically correct and fully consistent with Congress's objective of preventing parasitic lawsuits." *Id.*

This Court should resolve this conflict in the courts of appeals.

B. This Court Should Reject The "Supported By" Interpretation

This Court should reject the Sixth Circuit's expansive view of "based upon." Instead, an action should only be regarded as "based upon" a public disclosure where the relator "has actually derived from that disclosure the allegations upon which his qui tam action is based." *Siller*, 21 F.3d at 1348. That view is the most logical interpretation of the statute's plain text and certainly serves Congress's goal of preventing "parasitic" lawsuits by persons seeking to take advantage of publicly available information.

The "based upon" language traces back to congressional reaction to this Court's decision in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943). In that case, the Court permitted a *qui tam* suit to proceed under the original 1863 Act against government contractors who had engaged in a collusive bidding scheme. Prior to the suit, the bidders had been criminally indicted for the same misconduct to which they eventually plead *nolo contendere*. The *qui tam* plaintiff *copied* the government's indictment and filed his own suit. The *Marcus* Court permitted the opportunistic suit, finding that the lawsuit would enable the government to recover penalties over and above the criminal penalty. *Id.* at 545.

Congress quickly acted to amend the FCA in light of *Marcus* to prevent such opportunistic suits in the future. *See John Doe*, 960 F.2d at 321 ("*Marcus* represents the high-water mark for parasitic *qui tam* actions."). In less than a year, Congress had adopted amendments tightening the availability of the suits and the President had signed them into law. *See* Act of December 23, 1943, 57 Stat. 608, *recodified in* 31 U.S.C. §3730(b)(4) (superseded). Specifically, the provisions barred any *qui tam* suit that was "based on evidence or information the Government had when the action was brought." 31 U.S.C. §3730(b)(4) (superseded). Thus, the legislation was designed to prevent *qui tam* plaintiffs from taking advantage of information that the government already had when filing a false claims law suit.

The present language of the public disclosure bar, including "based upon," was adopted as part of the 1986 amendments to the FCA. Responding to concerns that the FCA had been restricted too much, Congress loosened restrictions on the use of *qui tam* suits in those Amendments. Specifically, Congress indicated that the 1986 amendments were designed "to enhance the Government's ability to

recover losses sustained as a result of fraud against the Government." S. Rep. No. 345, 99th Cong., 2d Sess., at 1, *reprinted in* 1986 U.S.C.C.A.N. 5266.[2] At that point, "fraud against the Government was apparently so rampant and difficult to identify that the Government could use all the help it could get from private citizens with knowledge of fraud." *Siller*, 21 F.3d at 1347 (quoting *United States ex rel. LaValley v. First Nat'l Bank of Boston*, 707 F. Supp. 1351, 1355 (D. Mass. 1988)). Among other things, the amendments added the "original source" exception to the public disclosure bar.

What is apparent from this history is that Congress has attempted to find a balance between promoting the use of *qui tam* lawsuits as a means to combat corruption while at the same time deterring wholly parasitic and opportunistic FCA lawsuits. *See Dunleavy*, 123 F.3d at 740 (discussing Congressional attempts to find a balance). The balance that Congress ultimately settled on, however, has been placed in jeopardy by those courts of appeals, like the Sixth Circuit, that have taken the phrase "based upon" and essentially substituted "similar to" or "supported by." That construction is inconsistent with the plain language of the provision and swings the pendulum to the point where legitimate *qui tam* lawsuits are completely barred.

As with any statutory construction question, this Court begins with the text and "assume[s] that the legislative purpose is expressed by the ordinary meaning of the words used." *United States v. James*, 478 U.S. 597, 604 (1986) (internal quotation omitted). As the *Siller* court noted, "based

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[2] Congress, in large part, was reacting to the Seventh Circuit's decision in *United States ex rel. Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984).

upon" should be construed to mean "derived from," meaning that a false claims act suit should only be barred if the plaintiff's *qui tam* allegations are actually derived from publicly available information, as they were, for example in the *Marcus* case. *Siller*, 21 F.3d at 1348. Quoting *Webster's Third New International Dictionary* at 180 (1986), the court noted that to "base upon" means to "use as a basis for." *Id.* Previous allegations that somehow "support" or are "similar to" the allegations in the *qui tam* lawsuit are a far cry from allegations that form the "basis" for that lawsuit. *See Siller*, 21 F.3d at 1349 ("We are unfamiliar with *any* usage, let alone a common one or a dictionary definition, that suggests that 'based upon' can mean 'supported by.'").

As Judge Becker has also pointed out, this Court's decision in *Saudi Arabia v. Nelson*, 507 U.S. 349 (1993) is instructive. In that case, the Court determined when an "action" would be "based upon a commercial activity" for purposes of the Foreign Sovereign Immunities Act of 1976. There, the Court stated: "In denoting conduct that forms the 'basis,' or 'foundation,' for a claim, the phrase is read most naturally to mean those elements of a claim that, if proven, would entitle a plaintiff to relief under his theory of the case." *Id.* at 357. The Court rejected the notion that such an action would be based upon commercial activity where it merely had a "connection to" commercial activity. In that case, the claim was related to commercial activity, but was not "derived from" those activities. *Mistick*, 186 F.3d at 396 (Becker, J., dissenting); *see also id.* at 397 n.4 (Becker, J., dissenting) (discussing analogy to "derivative work" doctrine in copyright under which a derivative work must be substantially copied from a prior work).

Even common legal discourse and usage shows that the expansive interpretation of "based upon" is misplaced. An

affidavit, for example, that purports to be "based upon" personal knowledge is an affidavit that reports things that were derived from the affiant's personal observations. *See* Vogel, *The Public Disclosure Bar Against Qui Tam Suits*, 24 Pub. Cont. L.J. 477, 499 (1995).

Finally, reading "based upon" more narrowly than the Sixth Circuit has done here is fully consistent with Congress' desire to prevent parasitic lawsuits, post-*Marcus*, while at the same time preserving the False Claims Act as a viable anti-fraud tool (consistent with Congress' purpose in enacting the 1986 Amendments). A *qui tam* lawsuit that contains allegations that are similar to those previously disclosed "but were not actually derived from those public disclosures, simply is not, in any sense, parasitic." *Siller*, 21 F.3d at 1348.

C. The *Qui Tam* Suit In This Case Was Not "Based Upon" Previous Public Allegations

Finally, there is no question that the choice between whether "based upon" means "supported by" or not is dispositive in this case. The prior public disclosures in this case amounted to product liability allegations in state court tort lawsuits. Pet. App. 8a. Those tort suits contained no allegation that the ultimate product, which may or may not have been defective, deviated in any way from any design previously approved by the government. The latter was the basis for the *qui tam* lawsuit here. Following established circuit precedent regarding the meaning of "based upon," the Sixth Circuit determined that the *qui tam* allegations were broadly "supported by" the earlier public disclosures. That outcome would plainly have been different in the Fourth or Seventh Circuits because there is simply no allegation that the

Petitioners "derived" the basis of their lawsuit from those previous disclosures.

II. THIS COURT SHOULD ADDRESS THE CONFUSION IN THE CIRCUITS REGARDING WHAT CONSTITUTES "ALLEGATIONS OR TRANSACTIONS" FOR PURPOSES OF THE PUBLIC DISCLOSURE BAR

In addition to the dispute about whether a later *qui tam* suit is "based upon" prior publicly disclosed "allegations or transactions," there is confusion in the circuits regarding how to determine whether the previous information constitutes "allegations" of fraud or fraudulent "transactions" such that the government was, essentially, on notice regarding the relator's eventual claims. The statute states that an action is barred if it is "based upon the public disclosure of allegations or transactions in [certain proceedings]." The statute does not indicate what quantum of information must have been publicly disclosed in order to constitute the "allegations or transactions" upon which the later suit must be based in order to be barred.

Courts, including the Sixth Circuit, have interpreted the phrase "allegations or transactions" to describe alternate ways in which there can be public disclosure of fraud. The D.C. Circuit developed a mathematical formula, adopted by the Sixth Circuit, to describe the inquiry — "X + Y = Z." *See United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994). "Z" represents a direct allegation of fraud, which is publicly disclosed. Such a disclosure would be sufficient to meet the requirements of the public disclosure bar. Alternatively, there could be a disclosure of the essential elements of a fraudulent "transaction": the true state of facts ("X") and the

misrepresented state of facts ("Y") ("X+Y=Z"). *Id.* From the combination of "X + Y," the "readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed." *Id.* at 654. Once the court finds either the public disclosure of the allegation of fraud or the public disclosure of the fraudulent transaction, the court can apply the jurisdictional bar only if it determines that relator's complaint is "based upon" that public disclosure. *Id.*

The Sixth Circuit held that prior state-law product liability lawsuits provided sufficient prior public disclosure of the specific allegation of fraud at issue in Petitioners' lawsuit ("Z"). In addition, the Sixth Circuit found that the essential elements of the fraudulent transaction at issue in Petitioners' lawsuit ("X+Y") had also been disclosed. The Sixth Circuit's first conclusion is flatly inconsistent with decisions of the Ninth and DC Circuits and is also inconsistent with the purposes behind the FCA. Similarly, the Sixth Circuit's finding of disclosure of a "fraudulent transaction" is inconsistent with the results reached in similar cases in other circuits and represents a departure from the principles behind the FCA.

A. The Sixth Circuit's Determination That Allegations Of The Fraud Alleged In This Case Had Been Publicly Disclosed Is Inconsistent With The Decisions Of Other Circuits And With The Purpose Of The Public Disclosure Bar

The Sixth Circuit determined that there was public disclosure of the Petitioners' "allegations" of Medicare fraud (the "Z") by virtue of *general* allegations of fraud on the FDA previously asserted against Medtronic by different parties in different legal actions. The Sixth Circuit acknowledged that the prior fraud allegations involved a

"slightly different type of fraud" than the fraud alleged by Petitioners. Pet. App. 10a. Although Petitioners take issue with the use of the qualifier "slightly," there is no disputing that the allegations were of "different types." Petitioners alleged in their *qui tam* suit that the Medicare system was defrauded into paying for leads that were secretly and illegally redesigned after FDA approval. The prior allegations "stated that the leads were not as safe as had been reported to the FDA" and also alleged "fraudulent manufacture and design deviations." Pet. App. 10a.[3]

Notwithstanding its acknowledgment that the frauds were of "different type[s]," the Sixth Circuit held that the prior "allegations were sufficiently general that they *could* encompass the fraud alleged in the *qui tam* action." Pet. App. 10a (emphasis added). The Sixth Circuit was not concerned that there were no public allegations of the specific fraud alleged by Petitioners because, it held, the prior allegations were sufficient to put the government generally on notice of the "'possibility of fraud.'" *Id.*

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[3] Those alleged "design deviations" were not the kind of deviations at issue in this *qui tam* suit. The "design deviations" were alleged in *North v. Medtronic, Inc.*, a product liability suit filed in Washington under Washington's strict liability statute. *See* RCW 7.72.030(2). *North's* allegation parroted that statute, alleging that Medtronic's leads were defective and that as a result of those defects, the leads "deviated in a material way from the design specifications and performance standards of Medtronic." In other words, the "deviation" was the fact that the leads were defective. Neither *North* nor any of the other product liability lawsuits used the term "deviated" to allege that Medtronic made any design change, let alone a secret, post-FDA approval change to the platinum sputter specification.

In so holding, the Sixth Circuit placed itself directly at odds with the Ninth Circuit, which held in *United States ex rel. Foundation Aiding the Elderly v. Horizon West Inc.*, 265 F.3d 1001 (9th Cir. 2001) that prior "general allegations of fraud" are not sufficient to trigger the jurisdictional bar where they do not "'fairly characterize[]' the *kind* of fraud alleged" in the *qui tam* complaint. *Id.* at 1015-16 (emphasis added). *See also United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1033 (9th Cir. 1998) (in analyzing whether allegations of fraud were previously disclosed, court must determine whether there was public disclosure of fraud which was 'substantially similar to those disclosed in the earlier . . . action'"). The vague fraud generally alleged in the prior product liability lawsuits certainly does not "fairly characterize" the later, different fraud that Petitioners allege.

The Sixth Circuit is also at odds with the D.C. Circuit which, like the Ninth Circuit, looks to whether the publicly disclosed prior allegations "specifically identify the nature of the fraud" alleged in the subsequent *qui tam* suit. *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 687 (D.C. Cir. 1997) (applying jurisdictional bar because public disclosures "specifically identify the nature of the fraud" – *i.e.*, the "illegal retention of monies owed to the government and unauthorized administrative approval of the practice"). There is no dispute that the prior product liability allegations against Medtronic do not specifically identify the nature of the fraud Petitioners alleged in this lawsuit.

The Ninth and D.C. Circuits will not apply the jurisdictional bar unless the government has enough information "to adequately investigate the case and to make a decision whether to prosecute" the defendant for *the* fraud alleged in the *qui tam* complaint. *See Horizon West*, 265 F.3d at 1016; *Findley*, 105 F.3d at 688. The Sixth Circuit, in

contrast, requires a much smaller quantum of information – *i.e.*, the government need only have notice of the "possibility" of *a* fraud. In so holding, the Sixth Circuit is out of step with the Congressional intent behind the 1986 FCA amendments, which was designed to increase incentives for relators to bring *qui tam* suits and "to enhance the Government's ability to recover losses sustained as a result of fraud against the Government." S.Rep.No. 345, 99th Cong., 2d Sess. at 1-2, reprinted in 1986 U.S.C.C.A.N. at 5266-67. *See also False Claims Act Implementation: Hearing Before the Subcomm. on Admin. Law and Gov. Relations of the House Comm. on the Judiciary*, 101st Cong., 2d Sess. 3, at 6 (1990) ("The publication of general, non-specific information does not necessarily lead to the discovery of specific, individual fraud which is the target of the qui tam action.") (Statement of Sen. Grassley).

Whether the jurisdictional bar can be triggered by prior allegations of a "different type" of fraud is an important issue that warrants review by this Court.

B. The Sixth Circuit's Determination That Fraudulent Transactions Had Been Publicly Disclosed Is Inconsistent With The Decisions Of Other Circuits And With The Purpose Of The Public Disclosure Bar

As an alternative holding, the Sixth Circuit determined there was public disclosure of the essential elements of the fraudulent "transaction" (the "X+Y"). The Sixth Circuit did not *find* public disclosure of the "true state of facts" – *i.e.*, that Medtronic changed the product design after FDA

approval.[4] Instead, the panel found that the true state of facts, "X," could be *inferred* from allegations made in previous products liability lawsuits, including specifically the *North v. Medtronic, Inc.* case in King County, Washington. And while previous court decisions have stated that "Z" can be inferred from the true state of facts, "X," and the false state of facts, "Y," even though "X" and "Y" do not appear in the same public disclosure, the Sixth Circuit's inference here was yet another step removed. Here, the Sixth Circuit did what no court has ever done by inferring "X" through a series of separate allegations, *e.g.*, "A+B+C=X."

Neither Medtronic nor the Sixth Circuit's decision specifically points to a public disclosure of the true state of facts here. Instead, the Sixth Circuit held that the fact that Medtronic had changed the product design after FDA approval could be *inferred* from general *allegations* in prior product liability lawsuits that "Medtronic (1) told the FDA that it had cured the problems with the leads by using a platinum sputter coating, (2) engaged in fraudulent conduct in the manufacture of the leads, and (3) deviated from the design specifications." Pet. App. 8a. The one case that the Sixth Circuit mentions by name, *North*, was nothing more than a state law products liability lawsuit spawned by the leads' poor performance. "Platinum sputter" is mentioned only once in the *North* complaint – and it is in the context of explaining that not even the addition of platinum sputter solved the leads' prior performance problems. Neither *North* nor any of the other product liability lawsuits makes any other allegations about platinum sputter, and most importantly no specific

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[4] Obviously, the misrepresented state of facts – *i.e.*, that the leads Medtronic was selling were FDA-approved leads – was publicly disclosed.

allegations that Medtronic also secretly altered the product's platinum sputter specification after the FDA had approved the lead.[5]

The Sixth Circuit rationalized its decision by suggesting that public disclosures in different sources together can lead to a conclusion of fraud. It is one thing to hold that a fraud allegation can be inferred from the true state of facts found in one source and the false state of facts found in another, but it is something entirely different to hold that the government can be expected to cobble together separate sources of information to infer the true state of facts alone and then stack that inference onto the false state of facts to infer a fraud allegation. Here, no public document ever disclosed that Medtronic had changed its platinum sputter specification – the panel inferred that change by speculating about different allegations collectively.

The Sixth Circuit's decision on this point is inconsistent with the application of the "X + Y" framework in other circuits, some of which have refused to apply the jurisdictional bar where there is no evidence that the actual "X" and "Y" have been publicly disclosed. *See Horizon West*, 265 F.3d at 1016 (no jurisdictional bar because no disclosure of "misrepresented state of fact[s]"); *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512-14 (8th Cir. 1994) (true state of facts – *i.e.*, that defendants "intentionally understated the pension liability" was not "in

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[5] Moreover, the "fraudulent conduct" alleged in *North* and the other product liability lawsuits is not even close to Petitioners' alleged fraud. The product liability lawsuits alleged Medtronic concealed safety data. Petitioners alleged Medtronic concealed a design change after lead approval and in direct violation of the applicable Conditions of Approval.

the public domain"); *United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 648, 655-56 (D.C. Cir. 1994) (no disclosure of true state of facts – *i.e.*, that defendant had not worked on days he billed the government for working).

In *Springfield Terminal*, the genesis of the "X + Y" formulation, the D.C. Circuit made it clear that the ultimate point of determining that the true state and misrepresented state of facts existed was so that "readers and listeners may infer Z, i.e., the conclusion that fraud has been committed." 14 F.3d at 654. Thus, given that the true state of facts is available and the misrepresented state of facts is available, the government could infer that fraud had taken place and presumably make an informed decision whether to pursue an investigation.

The Sixth Circuit has taken the inference one step farther by saying that the true state of facts need not be itself apparent. But this flies in the face of the *Springfield Terminal* court's determination that the government only has adequate information "[w]hen X *and* Y surface publicly." 14 F.3d at 654. The true set of facts here, that Medtronic manufactured a product that did not conform to the specifications that had been approved by the FDA originally, were simply not available publicly. The Sixth Circuit's conclusion that the true state of facts themselves could be inferred from the allegations in a product liability lawsuit that had nothing to do with Medtronic's actions post FDA-approval takes the "X + Y" formulation and the quest for fraudulent "transactions" beyond the place that other courts of appeals, including the *Springfield Terminal* court, have gone. This Court should grant review to clarify this issue.

Furthermore, the Sixth Circuit's legal determination allowing the jurisdictional bar to be raised on a mere inference of the "true state of facts" (the "X") is contrary to the intent behind Congress's 1986 amendment to the FCA, which was designed to increase incentives for relators to bring *qui tam* suits and "to enhance the Government's ability to recover losses sustained as a result of fraud against the Government." S.Rep.No. 345, 99th Cong., 2d Sess. at 1-2, *reprinted in* 1986 U.S.C.C.A.N. at 5266-67. Like the Sixth Circuit's construction of the phrase "based upon," the decision on this point makes it impermissibly difficult for legitimate *qui tam* relators to bring their lawsuits.

Whether courts should be able to infer the "true state of facts" at all, let alone unreasonably as the panel did here, is an important issue that warrants review by this Court.

III. THIS CASE PRESENTS A RECURRING PROBLEM AND IS OF EXCEPTIONAL IMPORTANCE

False Claims Act lawsuits are the United States Government's most effective tool against fraud. *See Cook County, Illinois v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (the False Claims Act was written "expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government") (citation omitted); *Avco Corp. v. Dept. of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989) (the False Claims Act is "the government's primary litigative tool for the recovery of losses sustained as the result of fraud against the government"). As reported by the U.S. Department of Justice, FCA cases resulted in a recovery to the Government of $1.2 billion in 2002, $2.1 billion in 2003, and $555 million in 2004. The United States Department of Health and Human Services – the agency that oversees Medicare – has recovered

over $5 billion through the *qui tam* provisions of the FCA. FCA cases are becoming more frequent. In 2004, there were 415 *qui tam* cases as compared to 33 cases in 1987. That is just what Congress intended when it amended the FCA in 1986 to "encourage more private enforcement suits" and to "make the statute a more useful tool against fraud in modern times." Senate Report No. 345, 99th Cong., 2d Sess. 8, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269, 5288-89.

If allowed to stand, the Sixth Circuit's decision will have an opposite effect from what Congress intended – it will embolden companies that are willing to commit fraud against the Government and discourage private citizens with knowledge of that fraud from blowing the whistle. The Sixth Circuit's decision is the outlier. It is the first court of appeals to have ever raised the jurisdictional bar based on mere speculative inferences of misconduct or general allegations of fraud wholly different in type from the fraud the relator alleges.

As shown above by the citation of federal court of appeals cases from nearly every circuit, the interpretation and construction of the public disclosure bar is a regularly recurring event. And despite the "host of interpretive issues" raised by these cases and the continuing consternation that its interpretation causes in the courts of appeals, this Court has yet to address these perennially troublesome but important issues. This case presents the Court with a compelling opportunity to do so.

CONCLUSION

For the foregoing reasons, the petition should be granted and the court of appeals judgment reversed.

Respectfully Submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 03-4213

[Filed August 2, 2005]

LOUIS F. GILLIGAN, ET AL., Plaintiffs-Appellees,

v.

MEDTRONIC INCORPORATED, Defendant-Appellant.

BEFORE: COLE and ROGERS, Circuit Judges; and COHN*, District Judge.

ORDER

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the

* Hon. Avern Cohn, Senior United States District Judge for the Eastern District of Michigan, sitting by designation.

original panel members but also to all other active** judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

** Judge Sutton recused himself from participation in this ruling.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

No. 03-4213

[Filed April 6, 2005]

UNITED STATES ex rel.	)
LOUIS F. GILLIGAN;	)
GREGORY M. UTTER	)
Plaintiffs/Relators-Appellees,	)
	)
v.	)
	)
MEDTRONIC INC.,	)
Defendant-Appellant.	)
	)

BEFORE: COLE and ROGERS, Circuit Judges; and COHN*, District Judge.

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati
No. 98-00248
S. Arthur Spiegel, District Judge

* Hon. Avern Cohn, Senior United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINION

R. GUY COLE, JR., Circuit Judge. Relators Louis F. Gilligan and Gregory M. Utter brought an action on behalf of the United States, under the False Claims Act, against Medtronic, Inc. ("Medtronic"), alleging Medicare fraud. Medtronic moved to dismiss the action on three grounds: (1) lack of subject matter jurisdiction under the False Claims Act; (2) failure to state a claim upon which relief could be granted; and (3) *res judicata*. The district court denied the motion as to all three claims. Medtronic thereupon filed a motion for leave to appeal the district court's denial of its motion to dismiss, which this Court granted. Medtronic now argues that the district court erred in denying the motion to dismiss. Because we find that the claims in this action were previously disclosed and trigger the public disclosure bar of the False Claims Act, we hold that the district court did not have subject matter jurisdiction and that dismissal was appropriate. Accordingly, we **REVERSE** the judgment of the district court and **REMAND** for proceedings consistent with this opinion.

I. BACKGROUND

Defendant-Appellant Medtronic is a medical-device manufacturer. Medtronic manufactures four types of heart pacemaker leads which are the subject of this litigation: Models 4004, 4004M, 4504, and 4504M. In 1988, Medtronic filed an application with the FDA for Premarket Approval of Models 4004 and 4504. The FDA approved the devices in a letter stating "[f]ailure to comply with the conditions of approval invalidates this approval order." The FDA attached the conditions of approval, which included a requirement that the company submit a supplemental Premarket Approval application "[b]efore making any change affecting the safety or effectiveness of the device." The conditions also required

that the company submit annual reports that identify changes to the product, regardless of the changes' impact on safety or effectiveness, stating that "[c]ontinued approval of this PMA is contingent upon the submission of post-approval reports . . . ."

In 1989, Medtronic changed the coating of two of the leads to a platinum sputter coating. The company filed supplemental applications for Premarket Approval for the subject leads, Models 4004M and 4504M. After the FDA approved the applications, Medtronic altered the design specifications of the two leads, changing the thickness and coverage of the platinum sputter coating. Medtronic did not file a new Premarket Approval application or identify the change in the annual post approval report filed with the FDA. However, the FDA's conditions of approval did not specify a required platinum sputter coating thickness or coverage. Furthermore, Medtronic did not submit information to the FDA in the premarket approval process that specified the new thickness or coverage of the platinum sputter coating.

Thereafter, a large number of the leads manufactured by Medtronic malfunctioned and had to be replaced. On the basis of this malfunction, relators Gilligan and Utter brought various products liability actions on behalf of individuals who used the malfunctioning leads. In these actions, the attorneys alleged, among other things, "fraud on the FDA" claims. The claims related to Medtronic's alleged misrepresentations to the FDA regarding the safety of the platinum-sputter-coated leads, fraud surrounding the manufacture of the leads, and deviation from design specifications.

Based upon the knowledge they gained through litigation of these product liability actions, Gilligan and Utter brought a *qui tam* action on behalf of the United States under the False

Claims Act. They alleged that: Medtronic sold leads to physicians and hospitals, which then implanted the leads and billed Medicare for their services; Medtronic did not have FDA approval for the devices because it altered the coating after approval; and by selling the leads to doctors and hospitals, Medtronic caused the submission of false claims to Medicare. This submission was allegedly a fraud on the government and therefore, Gilligan and Utter theorized, it formed the basis for a *qui tam* action under the False Claims Act.

In the district court, Medtronic filed a motion to dismiss based on the aforementioned three grounds: (1) lack of subject matter jurisdiction; (2) failure to state a claim; and (3) *res judicata*. The district court denied the motion.

II. ANALYSIS

A trial court's denial of a motion to dismiss for lack of subject matter jurisdiction is reviewed *de novo*. *United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 938 (6th Cir. 1997).

At the outset, we must determine whether the district court erred in denying Medtronic's motion to dismiss for lack of subject matter jurisdiction. The district court exercised subject matter jurisdiction over this suit under the False Claims Act. 31 U.S.C. § 3730 (b). The False Claims Act bars jurisdiction where "allegations or transactions" have been publicly disclosed in, *inter alia*, a civil hearing or administrative report. 31 U.S.C. § 3730(e)(4)(A). Where information has been publicly disclosed, the government has access to enough information to bring a civil action and the citizen-suit provision becomes unnecessary. This jurisdiction-stripping rule does not apply where the party bringing the

claim is the Attorney General or an "original source of the information." *Id.*

Relators in this case concede that they are not original sources. Therefore, this Court must determine whether the allegations or transactions at issue were publicly disclosed prior to the filing of the relators' complaint. To do so, the Court must determine first whether there has been any public disclosure of fraud, and second whether the allegations in the instant case are "based upon" the previously disclosed fraud. *United States v. Bledsoe*, 342 F.3d 634, 645 (6th Cir. 2003).

There are two parts to the theory that constitutes relators' *qui tam* suit. The first part is that the alteration of the platinum sputter coating rendered the leads manufactured by Medtronic unapproved by the FDA. The second part, which necessarily relies on the first claim, is that because the devices were rendered unapproved, the submission of Medicare claims by doctors constituted fraud. We will consider first whether there was any prior public disclosure of the allegations relating to the alterations in the platinum sputter coating. Then we will address whether the current case, including the allegation of Medicare fraud, is "based upon" the prior public disclosure, if any.

A. Public Disclosure

Generally speaking, we do not require specific disclosure of fraud to find public disclosure. So long as the information alleged is sufficient to put the government on notice of the likelihood of related fraudulent activity, the prior public disclosure requirement is satisfied. *Dingle v. Bioport Corp.*, 388 F.3d 209, 214-215 (6th Cir. 2004). There are two types of disclosures that this Court has found sufficient to put the government on notice of fraud. First, if information about

both a false state of facts and the true state of facts has been disclosed, we should find that there has been adequate public disclosure because fraud is implied. *Id.* at 212 (holding that if information about both a false state of facts and the true state of facts is available to the government, an inference of fraud is reasonable and the justification for the citizen suit provision of the False Claims Act is no longer applicable). Second, if there has been a public allegation of fraud, the Court should also find public disclosure. *Id.* A public allegation of fraud, regardless of the specificity of the allegation, is also sufficient to put the government on notice of the potential existence of fraud, thus eliminating the justification for the citizen-suit provision of the False Claims Act.

1. Disclosure of False State of Facts and True State of Facts

Relators allege that the prior disclosures do not contain information about the platinum sputter alterations. Relators further allege that these alterations, made after FDA approval of the leads, rendered the products unapproved. Under relators' theory of the case, the true state of facts would be that Medtronic altered the thickness and coverage of the platinum sputter coating after FDA approval. The false state of facts would be that the product was the same product previously approved by the FDA.

The false state of facts was previously disclosed. Medtronic represented to the public that the leads were FDA-approved, and implicitly, that it had complied with FDA regulations and guidelines sufficient to maintain the FDA-approved status of the product.

The true state of facts was also previously disclosed. In several prior products liability cases, including *North v. Medtronic, Inc.*, No. 97-2-16954-2SEA (Wash. Super. Ct. July 7, 1997), the plaintiffs alleged that Medtronic (1) told the FDA that it had cured the problems with the leads by using a platinum sputter coating, (2) engaged in fraudulent conduct in the manufacture of the leads, and (3) deviated from the design specifications. Relators argue that these allegations are insufficient to constitute prior disclosure of the allegations in the current *qui tam* action because the prior allegations did not specifically link Medtronic's alteration of the platinum sputter coating with the claims of fraudulent manufacture and deviation from design specifications. However, a specific link between pieces of information necessary to create an inference of fraud is not required.

This Court has previously held that public disclosures contained in different sources, which together provide information that leads to a conclusion of fraud, trigger the public disclosure bar. *See Dingle*, 388 F.3d at 213-14 (finding public disclosure where part of the relevant information came from a journal article and part came from a House of Representatives report). Here, the information necessary to create the specific inference of fraud was contained in two different parts of a complaint. Just as the government could reasonably infer fraud based on separate allegations in a journal article and a House report, the government could also reasonably infer fraud from allegations made in separate parts of a complaint.

Even if this inference were unreasonable, it was sufficient that prior publicly available cases mentioned both a change in the design specifications and fraud surrounding the manufacture of the leads, because these allegations, even each

taken alone, reveal the true state of facts: a change in the product design after FDA approval.

Therefore, since information was publicly available about the true state of facts and the false state of facts underlying the alleged fraud in the *qui tam* action, the jurisdictional bar of the False Claims Act requires dismissal of the current case.

2. Disclosure of Fraud

Even if this Court concluded that the false and true states of facts had not been disclosed, it could still find a prior disclosure of the fraud itself sufficient to trigger the jurisdictional bar of the False Claims Act. The relators argue that the prior allegations that Medtronic misrepresented how safe its leads were do not constitute the same fraud on the FDA that they alleged. Further, they argue, while the prior cases alleged only fraud on the FDA, this case alleges Medicare fraud.

However, in *Dingle*, we held that a specific allegation of fraud is not necessary. So long as the disclosed fraud puts the government on notice of the "possibility of fraud" surrounding the product or transaction, the prior disclosure is sufficient. *Dingle*, 388 F.3d at 214. For example, in *Dingle* a House Report identified FDA citations for "deviations" from the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* The report did not specifically identify these deviations; it merely stated their existence. *Id.* The Court found this to be sufficient to constitute notice of fraud under the False Claims Act. *Id.* The notice of deviations from the FDCA "allow[ed] a reader to strongly infer that BioPort was not producing its vaccine in line with the FDA requirements." *Id.*

Here, the prior allegations stated that the leads were not as safe as had been reported to the FDA. The prior allegations also alleged fraudulent manufacture and design deviations. The fraud alleged in the *qui tam* action is based on Medtronic's failure to disclose changes to the product as allegedly required bylaw, thus rendering the product unapproved by the FDA. While both allegations include claims of fraud on the FDA, the two types of fraud on the FDA are slightly different. However, the allegation of fraud on the FDA in relation to the leads in combination with the allegation of fraudulent manufacture and design deviation was sufficient to put the government on notice of the "possibility of fraud" surrounding the manufacture and design of the leads. The allegations provided enough information for the government to infer that Medtronic was not manufacturing the leads in line with FDA requirements and were therefore sufficient to put the government on notice of the possibility of fraud.

Further, although the allegations in the prior cases referred to a slightly different type of fraud than the fraud alleged in the current case, such allegations were sufficiently general that they could encompass the fraud alleged in the *qui tam* action. The relators in *Dingle* argued that the House testimony and report did not refer to the same allegations of fraud as alleged in the *qui tam* action. *Id.* at 213. However, the *Dingle* Court recognized that, although the House testimony may have concerned a slightly different type of fraud, the information conveyed was more general and could have referred to several types of fraud, including the fraud at issue in the *qui tam* case. *Id.* Here similarly, the prior allegations of fraud on the FDA were sufficiently general, and like the allegations in *Dingle*, could have encompassed the claim of manufacturing fraud and design deviations surrounding the platinum sputter coating on the leads.

The prior allegations concerning Medtronic's misrepresentations to the FDA are sufficient to bar the relators' Medicare fraud claim, as well. The relators argue that Medtronic's changes to the platinum sputter coating rendered the leads unapproved by the FDA. Medtronic defrauded Medicare when it induced Medicare to pay for unapproved leads, the relators allege, because approval is a precondition for Medicare coverage. As the district court noted, a Medicare coverage rule "provides an inference that the marketing of non-FDA-approved devices would have an impact on Medicare claims." Although the district court concluded otherwise, we conclude that the prior allegations of fraud on the FDA notified the government of the possibility of Medicare fraud associated with these Medtronic products.

B. Based Upon the Disclosed Fraud

The next question before us is whether the claim is based upon the disclosed fraud. This Court has held that a complaint is "based upon" the public disclosure where it is "supported by [the public disclosure] and includes any action based even partly upon public disclosures." *United States ex rel. Jones v. Horizon Healthcare Corp*, 160 F.3d 326, 332 (6th Cir. 1998) (internal quotations omitted); *see also Bledsoe*, 342 F.3d at 646; *McKenzie*, 123 F.3d at 938.

The district court found that jurisdiction was proper because the *qui tam* action was not based upon prior allegations of Medicare fraud. Specifically, the district court found that "defendant has not shown a public record which specifically alleges that a particular patient had a Model 4004/M lead implanted *and* that this procedure and implant were paid for by Medicare." (emphasis in original). However, the Medicare fraud claim necessarily relies on the FDA fraud claim. Without FDA fraud rendering the leads

unapproved, there could not have been Medicare fraud, because the submission of Medicare claims for implantation of the leads would have been valid. Therefore, the Medicare fraud claim is based on the public disclosure of fraud on the FDA and jurisdiction under the False Claims Act was inappropriate.

III. CONCLUSION

For the preceding reasons, we **REVERSE** the judgment of the district court and **REMAND** for disposition consistent with this Court's opinion.

APPENDIX C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

NO. C-1-98-248

[Filed June 6, 2003]

UNITED STATES OF AMERICA, ex rel. Louis F. Gilligan, et al., Relators,	)
v.	)
MEDTRONIC, INC., Defendant.	)

ORDER

This matter is before the Court on Defendant's Motion to Dismiss (doc. 65), Relators' Memorandum in Opposition to Defendant's Motion to Dismiss (doc. 82), Defendant's Reply (doc. 89), Defendant's Motion to Disqualify Louis F. Gilligan, Esq., Gregory M. Utter, Esq., and Keating, Meuthing & Klekamp, P.L.L. from Appearing Herein as Counsel (doc. 67) and Louis F. Gilligan's and Gregory M. Utter's Memorandum in Opposition to Medtronic's Motion to Disqualify (doc. 74).

MOTION TO DISQUALIFY

As a preliminary matter, the Court will dispense with Defendant's Motion to Disqualify (doc. 67).

The Court notes Defendant's concern about "hybrid representation" in which Gilligan and Utter represent themselves *pro se* but also have other attorneys representing them (Id.). The Court shares Defendant's concern about the confusion this may cause during proceedings in the courtroom. The Court also notes that this hybrid representation may be permitted at the Court's discretion. *See United States v. Mosley*, 810 F.2d 93, 98 (6th Cir. 1987). The Court further determines that allowing Gilligan and Utter to participate with their counsel in chamber conferences held by the Court will not prejudice Defendant. The Court will therefore allow Gilligan and Utter to participate in all such chamber proceedings (e.g. status and settlement conferences) but not in courtroom proceedings (e.g. hearings) and proceedings before a jury, where they will be solely represented by their counsel.

The Court also takes note of Defendant's argument that Gilligan and Utter should be disqualified pursuant to Ohio Disciplinary Rules because of the possibility that they will be called as witnesses. The Court's determination that Gilligan and Utter will not be permitted to act as counsel during any proceedings in the courtroom before the Court or before a jury sufficiently addresses these concerns.

FACTS

The problems associated with the pacemaker leads involved in this case have been fully reported in numerous opinions in this Circuit and others. *See, e.g., Kemp v.*

Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000). Therefore, in pursuit of judicial economy, this Court will provide an abbreviated recitation of the facts.

Defendant produces cardiac pacemaker leads, in particular, Model 4004/M and 4504/M leads (hereinafter, "pacemaker leads") for use in human hearts (doc. 82). These leads have been the subject of much product liability and negligence litigation. Essentially, Relators allege that Medtronic knew a method of testing it conducted, named "Solution A" testing, was not a reliable way to test the performance of pacemaker leads, but falsely represented to the Food and Drug Administration (hereinafter, "FDA") that it was effective. Relators further allege that Medtronic falsely told the FDA that canine testing was unnecessary because the Solution A testing was effective. Relators also allege that earlier pacemaker leads malfunctioned because of insulation failures and that Medtronic falsely represented to the FDA the nature of the coating process it used to cure this problem (doc. 65). Relators now assert that through various actions, Medtronic caused doctors, hospitals, and other health care providers to submit false claims for Medicare reimbursement in connection with the use of Medtronic Model 4004/M and 4504/M leads (doc. 82).

The Parties submitted extensive, detailed briefs. The Court has carefully reviewed them and will provide a concise summary of the Parties' arguments.

LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO STATE A CLAIM

Subject Matter Jurisdiction-31 U.S.C. § 3730(e)(4)(a)

A Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction attacks a plaintiff's cause of action in one of two ways: facially or factually. Fed. R. Civ. P. 12(b)(1); *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). A facial attack challenges the sufficiency of the complaint itself. On such an attack, the Court must take all material allegations in the complaint as true and construe them in a light most favorable to the non-moving party. *Ritchie*, 15 F.3d at 598 (citing *Scheuer v. Rhodes*, 416 U.S. 232, 235-37 (1974)). Defendant brings its Motion to Dismiss as a facial attack, and as such, the Court will analyze it in this fashion.

Defendant argues that, where the allegations of fraud have been publicly disclosed, the False Claims Act (hereinafter, "FCA") prohibits *qui tam* actions unless Relator is the original source of allegations (doc. 65). According to Defendant, the allegations of fraud in this case have been subject to public disclosure both in civil litigation and FDA administrative reports (*Id.*). Defendant named seventeen civil cases in which they argue public disclosure occurred. In addition, Defendant alleges that three administrative reports from the FDA and five Freedom of Information Act requests resulted in public disclosure (*Id*). Defendant argues that public disclosure is not required to have been specific or even to have used the word "fraud" but must have merely "presented enough facts to create an inference of wrongdoing" (*Id.*) (citing *Jones v. Horizon Health Care*, 160 F.3d 326, 332 (6th Cir. 1998)).

Defendant further argues that Relators are not original sources because they fail to satisfy both prongs of the original source test. According to Defendant, to satisfy both these prongs, Relators must have "direct and independent knowledge" of the information on which *qui tam* allegations are based (Relators do not allege having this knowledge); and Relators must have voluntarily provided the relevant information to the government before filing (Relators do not show that they have done this) (*Id.*) (*citing Jones* 160 F.3d at 326; *United States ex. rel. McKenzie v. Bellsouth Tellecomms.*, 123 F.3d 935 (6th Cir. 1997) ; *United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913 (D.C. Cir. 1999); *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.2d 1156 (10th Cir. 1999)). As Relators apparently concede this point, the Court will not engage in an analysis of Relators as original sources.

Relators argue Defendant did not satisfy the criteria (particularly public disclosure requirement) which must be met in order for the FCA's jurisdictional bar to be triggered (doc. 82). Relators allege that Defendant's failure to disclose the platinum sputtering manufacturing changes invalidated the leads approval (*Id.*). According to Relators, this rendered the claims for Medicare reimbursements made on the leads false under the FCA (*Id.*). Relators assert that Defendant did not identify any instances where Relators' platinum sputtering invalidation claim was publicly disclosed (*Id.*). Relators argue that Defendant's assertion that the sputtering invalidation claim was disclosed in *Kemp v. Medtronic* fails because all the documents cited by Defendant were filed or issued after Relator's April 1, 1998 *qui tam* Complaint (*Id.*). According to Relators, Plaintiffs' amended complaint in *Kemp* was filed January 19, 1999; Plaintiffs' Memorandum in Opposition to Summary Judgment in *Kemp* was filed September 11, 1998; and the Sixth Circuit Opinion in *Kemp* was filed

November 1, 2000. According to Relators, their false testing allegation was not disclosed in the product liability suits because that case made different assertions than those in this case and the false claims allegations do not arise out of the allegations of product liability (*Id.*).

Relators' argument that there has been no public disclosures relies on the logic underlying the D.C. Circuit's decision in *United States ex rel. Springfield Terminal Co. v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994). As noted by Relators, the Springfield Court reduced the *qui tam* allegations or transaction analysis to an algebraic formula.

> If X [allegations of fraud on the FDA] + Y [the fact that there is no Medicare coverage for devices not approved by the FDA] = Z, Z represents the allegation of [Medicare] fraud and Y represents its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

143 F.3d 645.

The Sixth Circuit has adopted such logic and further concluded that

> *Qui tam* actions are barred only when enough information exists in the public domain to expose the fraudulent transaction (the combination of X and Y), or the allegation of fraud (Z).

United States ex rel. Jones v. Horizon Healthcare Corp., 160 F.3d 236, 331 (6th Cir. 1998).

Relators assert that its false testing allegation falls into the following pattern:

> X is Medtronic's misrepresentation regarding the testing conducted on the leads rendered their FDA approval improper.
>
> Y represents the fact that there is no right to Medicare reimbursement for non-FDA approved devices, and the fact that Medtronic held the leads out as FDA approved, which caused health care providers to submit false claims for Medicare reimbursement on the leads.
>
> Z stands for the conclusion that Medtronic's misrepresentations regarding the testing conducted on the leads caused false claims for Medicare reimbursement to be submitted.

Relators admit that portions of X have been made public, but assert that the facts contained in Y have never before been publicly disclosed (doc. 82). Relators list the elements of "Y" that have never been disclosed: 1.) Medtronic's misrepresentations to the FDA regarding the testing conducted on the pacemaker leads rendered their premarket approval (hereinafter, "PMA") improper, 2.) that Medtronic's failure to disclose the results of the canine tests to the FDA invalidated the PMA approval, 3.) that non-FDA approved products are not subject to Medicare reimbursement, and 4.) Medtronic's actions caused Medicare claims on the leads to be improperly submitted (*Id.*).

Relators conclude that neither Z nor the elements of Y have been publicly disclosed prior to this suit. Thus, according to Relators, the Court must conclude that Relator's

testing misrepresentation allegation does not satisfy the "allegations or transactions" component of Section 3730(e)(4)(A) necessary to deprive this Court of jurisdiction.

Although the Court agrees with Defendant that Relators' claims may be characterized as "novel," for the reasons that follow, the Court will deny Defendant's Motion to Dismiss. The Court carefully reviewed the documents to which Defendant cited when identifying the cases it argued resulted in public disclosure which would bar Relators' instant *qui tam* litigation. The Court further carefully reviewed the disclosure statement made by the Relators when they filed the instant *qui tam* litigation (doc. 3). As a result of the review of the documents provided by Defendant, the Court acknowledges the existence of detailed public disclosure of fraud on the FDA including disclosures concerning Defendant's alleged failure to properly represent its testing methods and potential problems with the coating process. However, the Court also notes the specific nature of Relators' allegations of Medicare fraud in its disclosure statement. Relators described, in detail, the process which parties seeking Medicare reimbursement are required to follow. Relators further alleged the existence of specific individuals in whom Medtronic pacemakers were implanted and for whom claims were made to Medicare. Finally, Relators specifically alleged that these facts resulted in damage to the United States totaling Five Hundred Million ($500,000,000) Dollars.

It is on these allegations that Relators' argument rests and thus, the public disclosure necessary to bar their instant litigation does not depend on the refuting of disclosure of fraud on the *FDA*. Instead, the Court must determine whether these instances of public disclosure of fraud on the FDA were sufficient to satisfy Defendant's burden of demonstrating that Relators' claims of fraud on *Medicare* have been previously

publicly disclosed. Given its mandate to construe material facts in a light most favorable to the Relators, and its mandate to read expansively the FCA, the Court finds that Defendant has not satisfied its heavy burden to demonstrate that the cases Defendant cited add "Y" to "X" in such a way that would require the Court to come to answer "Z" (Defendant misrepresented testing results which resulted in false claims being submitted to Medicare). In other words, Defendant failed to *demonstrate* to this Court that disclosures of fraud on the FDA *necessarily* gave rise to notice of allegations that Defendant committed fraud on Medicare which would render Relator's Complaint insufficient. The Court also finds that Defendant has not demonstrated that the cases it cited explicitly disclose "Z" in such a way that the Court must dismiss Relator's Complaint as insufficient. As such, Defendant has not demonstrated that the Court's jurisdiction is foreclosed by 31 U.S.C. § 3730(e) (4) (A).

The Court takes note of Defendant's argument that the relevant Medicare coverage rule (that non-FDA approved devices are not covered by Medicare) are published in various public documents which provides an inference that the marketing of non-FDA approved devices would have an impact on Medicare claims (doc. 89). The Court agrees that this fact provides some fortification for the "Y" element in the algebraic formula. However, in describing the inference as obvious, Defendant is asking the Court to conclude that the elements of fraudulent FDA certification, where there is no Medicare coverage for non-FDA approved devices available, results in public disclosure of Medicare fraud even without the addition of a prior public disclosure of *specific* allegations of Medicare fraud based on the implantation of a non-FDA approved device. In other words, Defendant has not shown a public record which specifically alleges that a particular patient had a Model 4004/M lead implanted *and* that this

procedure and implant were paid for by Medicare. Given the Court's mandate to construe all allegations in the light most favorable to Relators, it cannot assume public disclosure of fraudulent Medicare claims, without allegations of specific Medicare patients being treated with these particular pacemaker leads.

Defendant's reliance on *United States ex rel. McKenzie v. Bellsouth*, 123 F.3d 935 (6th Cir. 1997) is misplaced. In finding former public disclosure, the *McKenzie* Court cited a previously filed *qui tam* action against Bellsouth based on nearly identical allegations. McKenzie attempted to distinguish her suit from the previously filed *qui tam* suit. In doing so, McKenzie relied on the fact that her allegations only involved South Central Bell's practices in Tennessee where the previously filed suit alleged violations in Florida, Georgia, North Carolina and South Carolina. The Sixth Circuit rejected this argument.

As Relators in this case rely on more substantial distinctions between the instant case and previously filed product liability cases, the Court does not find the *McKenzie* case to be instructive.

Rule 12(b)(6) Failure to State a Claim

A Rule 12(b)(6) motion to dismiss requires the Court to determine whether a cognizable claim has been pleaded in the complaint. The basic federal pleading requirement is contained in Fed. R. Cir. P. 8(a), which states that, a pleading "shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." *Westlake v. Lucas*, 537 F.2d 857, 858 (6th Cir. 1976). In its scrutiny of the complaint, the Court must construe all well-pleaded facts liberally in favor of the party opposing the motion. *Scheuer*

v. Rhodes, 416 U.S. 232, 236, 94 S.Ct. 1683, 1687 (1974). Rule 8(a)(2) operates to provide the defendant with "fair notice of what plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99 (1957). A court examines a complaint in light of the objectives of Rule 8 using the standard articulated in *Jones v. Sherrill*, 827 F.2d 1102, 1103 (6th Cir. 1987):

> In reviewing a dismissal under Rule 12(b)(6), the court must accept as true all factual allegations in the complaint. *Windsor v. The Tennessean*, 719 F.2d 155, 158 (6th Cir. 1983), *cert. denied*, 469 U.S. 826 (1984). The motion to dismiss must be denied unless it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim which would entitle her to relief. *Id.* at 158; *Conley v. Gibson*, 355 U.S. 41 (1957).

Jones, 824 F.2d at 1103.

The admonishment to liberally construe the plaintiff's claim when evaluating a Rule 12(b)(6) dismissal does not relieve a plaintiff of his obligation to satisfy federal notice pleading requirements and allege more than bare assertions of legal conclusions. Wright, Miller & Cooper, Federal Practice and Procedure: § 1357 at 596 (1969). "In practice, a complaint . . . must contain either direct or inferential allegations respecting all of the material elements [in order] to sustain a recovery under some viable legal theory." *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984), *cert. denied*, 470 U.S. 1054 (1985) (quoting *In Re: Plywood Antitrust Litigation*, 655 F.2d 627, 641 (5th Cir. 1981), *cert. dismissed*, 462 U.S. 1125 (1983)); *see also Sutliffe, Inc. v. Donovan Companies, Inc.*, 727 F.2d 648, 654 (7th Cir. 1984); Wright, Miller & Cooper, Federal Practice

and Procedure: § 1216 at 121-23 (1969). The United States Court of Appeals for the Sixth Circuit clarified the threshold Set for a Rule 12(b)(6) dismissal :

> [W]e are not holding the pleader to an impossibly high standard; we recognize the policies behind Rule 8 and the concept of notice pleading. A plaintiff will not be thrown out of court for failing to plead facts in support of every arcane element of his claim. But when a complaint omits facts that, if they existed, would clearly dominate the case, it seems fair to assume that those facts do not exist.

Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 437 (6th Cir. 1988).

Defendant argues that Relators' Complaint does not allege that Medtronic presented or caused to be presented claims to Medicare (doc. 65). According to Defendant, it does not submit claims to Medicare for cardiac devices (*Id.*). Defendant argues that Medtronic'sknowledge that another person would submit a false claim does not sufficiently establish liability (*Id.*). Defendant further argues that Relators' Complaint fails to allege falsity because there are no allegations that physicians submitted claims for services or medical procedures that they did not render (*Id.*). Defendant also argues that Relators' theory, that claims submitted by health care providers are false because of Defendant's failure to obtain FDA approval, does away with the FCA's requirements for false claims (*Id.*). According to Defendant, Relators have not alleged that any person certified (stated) to Medicare that Medtronic had complied with FDA regulations. Finally, Defendant argues that a claim itself must be false to be actionable under the FCA (*Id.*).

Relators argue that fraudulent/implied certification theories are well-recognized (doc. 82). According to Relators, the FCAwas written expansively to reach all types of fraud that might result in financial loss to government and courts have held that liability exists if a defendant falsely certifies compliance with statues resulting a government payment of a claim (*Id.*) (*citing Cook County, Illinois v. United States ex rel, Chandler*, 123 S.Ct. 1531 (2003)). Relators point to Sixth Circuit language as holding that a false implied certification may constitute a false claim even if the claim was not expressly false when filed (*Id.*)(*citing United States ex rel. Augustine v. Century Health Serv. Inc.*, 289 F.3d 409, 415 (6th Cir. 2002)). Relators further take issue with Defendant's "cause to be filed" argument (*Id.*). According to Relators, the precedent cited by Defendant in support of such argument is "bizarre" and more appropriate Supreme Court precedent held that the FCA was written to reach any person who knowingly assisted in causing government to pay claims grounded in fraud (*Id.*) (*citing United States ex rel. Shaver v. Lucas Western Corp.*, 237 F.3d 932 (8th Cir. 2001)).

Given the liberal pleading standards inherent in Rule 12(b)(6), the Court finds that Relators have sufficiently stated a claim upon which relief can be granted. The Court agrees with Relators that numerous courts have held that FCA liability exists if a defendant falsely certifies or impliedly certifies compliance with statutes and regulations that result in the government's payment of a claim. *See e.g. Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 766, 786-88 (4th Cir. 1999) ; *United States v. TDC Management Corp., Inc.*, 288 F.3d 421 (D.C. Cir. 2002); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997). The Court further agrees that the Sixth Circuit case, *United States ex rel. Augustine v. Century Health Serv. Inc.*, 289 F.3d 409, 415 (6th Cir. 2002) employs

language that makes it most clear that the Sixth Circuit approves of the "implied certification" theory.

Rule 12(b)(6) does not mandate that this Court test the ultimate truth of the allegations sounded in the Complaint. It only requires that the Court examine whether the allegations in the Complaint are sufficient to state a claim for relief. The Court also notes the mandate to expansively interpret the FCA as a way to encourage the filing of claims. Keeping this in mind, the Court finds that, even if doctors (but not Medtronic) physically provided the product (the pacemaker leads) and the service (implantation of the pacemaker leads) for which they requested reimbursement from the United States, because Relators allege that those products lost FDA approval, Relators adequately allege that the transaction retains the taint established when Medtronics failed to comply with FDA regulations.

The Court agrees with Relators that Defendant's reliance on *United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 2001) is misplaced. As noted by Relators, the Ninth Circuit did not find any connection between the "Certification of Assurances," which falsely represented that federal funds were properly used and the receipt of funds through a program run by the federal government (doc. 82) (*citing Hopper*, 91 F.3d at 1267.). Finally, the Court finds Defendant's "variety of tools argument" inadequate. The Court agrees that the FDA has a myriad of tools at its disposal and that Congress has charged the FDA with the responsibility of policing fraud in the device approval process (doc. 65). However, Defendant cites no precedent which clearly prohibits private litigants from "assisting" the FDA in its mandate to police this fraud. The Court further agrees with Relators that the precedent cited by Defendant is inapposite.

As noted by Relators, *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) involved state- law personal injury claims based on allegations of fraud upon the FDA in obtaining approval to market medical devices. The Court's decision that the claim in *Buckman* was preempted by federal law is soundly based on the concern about the possible dissonance between the FDA's regime and the tort law regimes of the fifty individual states. No such concern is present here, and thus *Buckman* provides little guidance to this Court.

In sum, the Court finds that, given the liberal pleading standards of Rule 12(b)(1) and 12 (b)(6) and its mandate to expansively interpret the FCA, Defendant has not successfully demonstrated public disclosure to the degree necessary to dismiss Relator's Complaint at this stage of the litigation. The Court also finds that Relators have adequately stated a claim for relief so as to survive Defendant's Motion to Dismiss.

FAILURE TO PLEAD A CLAIM WITH PARTICULARITY UNDER 9(B)

Rule 9(b) of the Federal Rules of Civil Procedure provides:

> In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge and other condition of mind may be averred generally. The purpose of Rule 9(b) is merely "to provide the defendant fair notice of the substance of plaintiff's claim in order that the defendant may prepare a responsive pleading." *Michaels Building Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 679 (6th Cir. 1988). The requirements of Rule 9(b) must be

> harmonized with Rule 8, which requires a "short and plain statement of the claim" and "simple, concise and direct allegations." *United States ex rel. Roby v. The Boeing Co.*, 184 F.R.D. 107, 110 (S.D. Ohio 1998).

Defendant argues that to satisfy Rule 9(b)'s requirement of pleading with particularity, Relators must at a minimum allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud (doc. 65) (*citing Advocacy Org. for Patients and Providers v. Auto Club Ins. Ass'n*, 176 F.3d 315, 322 (6th Cir. 1999)). According to Defendant, Relators' Complaint alleges nothing about claims submitted to Medicare, only mentions this case is about alleged false claims for payment submitted to Medicare, and that most of the allegations in the Complaint relate to Medtronic's dealing with the FDA (*Id.*). Defendant asserts that key allegations included in the Complaint have already been defeated in the Sixth Circuit after thorough review of the record which rejected Relators' "sputtering allegations" (*Id.*). Defendant further asserts that Relators have not named the "who, what, when, where" of the alleged Medicare fraud (*Id.*). Finally, Defendant asserts that it does not have factual information regarding Relators' Complaint and therefore Rule 9(b)'s requirement of particularity should not be relaxed (*Id.*).

Relators argue that the Sixth Circuit does not require Relators to specifically identify each claim submitted to Medicare on behalf of 68,000 Medicare patients (doc. 82). According to Relators, their Complaint provides Defendant with fair notice of substance of claims (*Id.*). Relators base this argument on the assertion that Relators allege that Medtronic was required to obtain approval from the FDA prior to marketing its leads (*Id.*) (*citing* Complaint ¶¶ 10, 11); they

allege that Medtronic misrepresented the nature and quality of its testing of the leads to the FDA. Therefore, the FDA's pre-market approval of the leads was obtained through factual misrepresentations (*Id.*) (*citing* Complaint ¶¶ 14-49) ; that the FDA's approval to market the leads was conditioned on continual compliance with FDA regulations and FDA approval (*Id.*) (*citing* Complaint ¶ 53); that Medtronic changed the sputtering specifications on the leads without submitting a supplement to documents filed with FDA or identify changes in annual report (*Id.*) (*citing* Complaint at ¶¶ 12, 13, 50-57); and thus, none of the 91,000 leads were approved by the FDA (*Id.*) (*citing Complaint* ¶ 57) .

Relators further assert, that they also plead with particularity that Medtronic misrepresented information gleaned from canine testing and Solution A testing (*Id.*) (*citing* Complaint ¶¶ 28, 43, 45). They base this on the allegation that Medtronic knew that procedures/devices were only reimbursable if the medical device is approved by the FDA (*Id.*)(*citing* Complaint ¶ 59); that Medtronic knew that majority of leads would be placed in Medicare patients and providers would seek reimbursement (*Id.*) (*citing* Complaint ¶¶ 59-62); and that their Complaint gives specific examples of patients given the leads and for whom providers pursued claims for reimbursement (*Id.*) (*citing* ¶ 64). Finally, Relators argue that they do not have to plead with particularity factual details within control of Defendant (here: a complete listing of hospitals which implanted the leads and the patients in whom they were implanted) (*Id.*).

The Court finds Defendant's arguments inconsistent. Defendant seems to argue that Relators have not pled with particularity in regard to fraud claims at the same time it argues that the Court can tell by the face of the Complaint that claims have already been publicly disclosed. The Court

further finds that Relators have satisfied the standard set forth by Rule 9(b). The numerous paragraphs in the Complaint and cited by Relators demonstrate that Defendant has a fair notice of the substance of Relators' claim such that allowed Defendant to prepare a thorough and well-reasoned responsive pleading.

RES JUDICATA

Res Judicata and collateral estoppel are judicially established doctrines that promote judicial efficiency, but are not to be rigidly applied. *Tipler v. E. duPont de Numours & Co.*, 443 F.2d 125, 128 (6th Cir. 1971). According to the Supreme Court, "a right, question or fact distinctly put in issue and directly determined by a court of common jurisdiction cannot be disputed in a subsequent suit between the same parties or their privies." *Montana v. United States*, 440 U.S. 147, 153 (1979). Collateral estoppel "must be confined to situations where the matter raised in the second suit is identical in all respects with that decided in the first proceeding and where the controlling facts. . .remained unchanged." *Commissioner v. Sunnen*, 333 U.S. 591, 599-600 (1948).

Res judicata bars claims if the following elements are present, "(1) a final decision on the merits by a court of competent jurisdiction; (2) a subsequent action between the same parties or their privies; (3) a claim in the subsequent action which was litigated or which should have been litigated in the prior action; and (4) an identity of the causes of action. *Bob Tatone Ford, Inc. v. Ford Motor Co.*, 140 F.Supp.2d 817, 823 (S.D. Ohio 2000) *citing Kane v. Magna Mixer Co.*, 71 F.3d 555, 560 (6th Cir. 1995).

Defendant asserts that the Court should apply Ohio's *res judicata* standards to the matter at hand (doc. 89). Defendant points to precedent establishing that the judgment of federal courts sitting in diversity shall have *res judicata* effect that a state court's judgment would (*Id.*)(*citing Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 508-509 (2001)). Defendant further asserts that the claim preclusive effect of *Kemp* is relevant to this determination, not what kind of claim this case is (*Id.*). Defendant also asserts that under Ohio law, *Kemp* was a final decision on the merits (*Id.*). Defendant acknowledges that there is no Ohio authority regarding whether dismissal on preemption grounds constitutes judgment on merits. However, according to Defendant, since statute of limitations dismissal has claim preclusive effect in Ohio, summary judgment on preemption should also (*Id.*). According to Defendant, both Judge Beckwith and the Sixth Circuit Court of Appeals rejected the platinum sputtering allegations under summary judgment standard (*Id.*).

Defendant further asserts that there is identity of parties because Gilligan and Utter and their clients, the *Kemps*, are in privity, that the *qui tam* allegations could have been litigated in *Kemp* and that *Kemp* and this action involve a common nucleus of operative facts (doc. 65)

Relators assert that there was no final decision on the merits in the *Kemp* case; that the action does not involve the same parties as the product liability action; that the false claim could not have been litigated in the *Kemp* case; and that the causes of action are not identical (doc. 82).

The Court questions the wisdom of charging attorneys with knowledge obtained from one client and barring attorneys from using or applying that knowledge when working for a subsequent client. In other words, the Court

finds that an agent's knowledge of the facts of a claim should not be used to bar another unrelated principal of the agent from asserting the claim.

Moreover, the Court agrees with Relators' analysis of the *res judicata* issue. First, the Court agrees that the earlier products liability cases in question were dismissed on preemption grounds and Judge Beckwith and the Sixth Circuit Court of Appeals never reached the merits of claim. In fact, the district court rejected as irrelevant all factual arguments attempting to circumvent federal preemption. The Sixth Circuit affirmed the district court's grant of summary judgment solely on the application of federal preemption.

The Court agrees with Relators that Sixth Circuit precedent clearly supports the contention that the merits of this case have not been judged. As cited by Relators, the Sixth Circuit in *Ervin v. Medtronic, Inc.*, 22 Fed. Appx. 462, 463 (6th Cir. 2001) opined that

> The district court erred in finding that claim preclusion applied to this case, as there was no final decision on the merits in the original proceeding. . .The district court never reached the merits of Ervin's product liability claim in her earlier lawsuit because it concluded that the action was preempted by federal regulations. We find this to be effectively the equivalent of a decision that the court lacked jurisdiction over the lawsuit. A court that does not have jurisdiction cannot reach the merits and therefore no final decision on the merits with preclusive effect results.

The Court further agrees this action does not involve the same parties (or their privies) as the product liability action.

As noted by Relators, the Kemps were represented by Gilligan and Utter as counsel for their product liability action. The Kemps did not bring False Claims Act claims and neither the Relators nor the United States could have brought the persbnal injury product liability claims pursued by the Kemps. In addition, Defendant has not sufficiently proved the proposition that Relators are in privity with the Kemps.

Furthermore the Court finds that the false claim allegations could not have been litigated in the *Kemp* product liability action. The Court finds it significant that during the time the United States was deciding whether to intervene and this false claims litigation was frozen, the *Kemp* litigation proceeded and was resolved in September of 2001 with the Supreme Court decision to deny *certiorari*.

Finally, the Court finds that the causes of action in these two cases are not identical. As noted by Relators, the Kemps brought state law causes of action against Medtronic for strict liability, negligence, and breach of warranty and sought compensatory and punitive damages for her physical and emotional damages. Relators, on behalf of the United States, have asserted a cause of action under 28 U.S.C. § 3730 seeking damages of Five Hundred Million ($500,000,000) dollars and other civil penalties based on allegedly false claims which caused the United States to make Medicare payments. Thus, these causes of action are not identical.

CONCLUSION

The Court finds that Defendant has not sufficiently demonstrated former public disclosure of Relators' claim of Medicare fraud to merit dismissal of Relators' Complaint. The Court further finds that Defendant has not shown that Relators' Complaint fails to state a claim upon which relief

can be granted or fails to sufficiently plead fraud with particularity. Finally, the Court finds that this action is not barred on *res judicata* grounds. Therefore, the Court hereby DENIES Defendant's Motion to Dismiss (doc. 65).

The Court further GRANTS Relators' request to participate with their counsel during chambers conferences with the Court, but DENIES Relators' request to represent themselves in any courtroom proceedings.

Finally, the Court notes that, in regard to its determinations concerning subject matter jurisdiction, failure to state a claim, and *res judicata*, this Order involves controlling questions of law as to which there may be substantial grounds for difference of opinion, and an appellate decision on any of the foregoing issues adverse to Relators may materially advance the termination of the litigation. Therefore, an immediate appeal from this Order pursuant to 28 U.S.C. § 1292(b), should be considered by Defendant.

SO ORDERED.

/s/ _____
S. Arthur Spiegel
United States Senior District Judge

Dated: 6/5/03

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No. 05-578

IN THE

Supreme Court of the United States

LOUIS F. GILLIGAN AND GREGORY M. UTTER,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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CORPORATE DISCLOSURE STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly-held company owns 10 percent or more of Respondent's stock.

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STATEMENT OF THE CASE

The False Claims Act. Petitioners Louis F. Gilligan and Gregory M. Utter brought this action under the *qui tam* provisions of the False Claims Act ("FCA"). The *qui tam* provisions permit private parties, known as "relators," to file suit under seal for themselves and for the United States alleging fraud against the federal government. *See* 31 U.S.C. § 3730(b). While the case is under seal, the United States is required to investigate the relator's allegations and decide whether to intervene and take over the litigation. *See id.* § 3730(b) & (c)(1)-(2). If the Government intervenes and takes over the litigation, the relator is entitled to receive up to 25 percent of whatever the Government recovers. *See id.* § 3730(d)(1). If the Government does not intervene, the relator can prosecute the action and receive up to 30 percent of any eventual recovery. *See id.* § 3730(d)(2).

The FCA, however, contains a number of exceptions to federal court jurisdiction over *qui tam* actions. *See id.* § 3730(e). One of those exceptions, the "public disclosure bar," is relevant here. It provides:

> No court shall have jurisdiction over an action . . . based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Id. § 3730(e)(4)(A) (footnote omitted).

Petitioners' *Qui Tam* Claims. Respondent Medtronic, Inc. manufactures medical devices. It formerly manufactured Models 4004 and 4004M pacemaker leads ("4004/M leads").

Petitioners allege that prior models of pacemaker leads suffered failures due to metal ion oxidation ("MIO"), and

that Medtronic tried to combat MIO problems by applying a "platinum sputter" coating to conductor coils within the 4004/M leads. Their Complaint alleges that Medtronic defrauded the FDA by representing that the Model 4004 and 4004M leads would be entirely coated with 500 angstroms of platinum sputter, but after gaining FDA approval, changed the engineering specifications to permit leads to be manufactured with platinum sputter coatings of between 100 and 1,000 angstroms and 85 percent coverage. According to Petitioners, as a result of this change, Medtronic marketed pacemaker leads that were different from what the FDA had approved.

Petitioners then contend that, by selling supposedly non-FDA-approved leads, Medtronic caused physicians and hospitals to unwittingly submit false claims to Medicare, because Medicare only covers implantation of FDA-approved devices. Medtronic did not submit any claims to Medicare, and Medicare did not pay Medtronic any money. Rather, it was the physicians and hospitals who used leads manufactured by Medtronic that submitted claims to Medicare, and Medicare paid them.

The Government investigated Petitioners' allegations, but declined to intervene. Petitioners have since prosecuted this action on their own.

This is not the first time that Petitioners have raised these claims. In fact, the Sixth Circuit previously rejected their claims as unfounded. In *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), decided while this *qui tam* action was under seal, Petitioners served as lawyers for plaintiffs in a products liability action. In that case, Petitioners made the same allegations as they made in their *qui tam* complaint concerning Medtronic's supposed marketing of non-FDA-approved leads. Affirming summary judgment for Medtronic in *Kemp*, the Sixth Circuit sharply rejected Petitioners' claims:

> Our review of the record leaves us firmly convinced that plaintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick *represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record.* Both in their briefs and in oral argument, plaintiffs repeatedly asserted that the Model 4004M specifications, as originally designed, call for a platinum sputter barrier a "uniform 500 angstroms thick." *Plaintiffs' statements find no support in the record. Indeed, we think that the record flatly contradicts plaintiffs' position.*

231 F.3d at 230 (emphasis added). In a word, in *Kemp*, the Sixth Circuit found Petitioners' accusations against Medtronic to be "specious." *Id.* at 231.

Accordingly, the Sixth Circuit has already concluded that a lead manufactured with between 100 and 1,000 angstroms of platinum sputter and 85 percent coverage satisfied the terms of FDA approval. *See Kemp*, 231 F.3d at 230-32. Petitioners' current assertion that "the leads Medtronic sold were different from the ones that had been approved by the FDA" (Pet. 5) is the very claim rejected in *Kemp*.[1]

Moreover, contrary to Petitioners' assertion, there is no record evidence that Medtronic ever changed the quality or

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[1] In addition, by bringing this *qui tam* action, Petitioners appear to have usurped an opportunity that belonged to the *Kemp* plaintiffs, and placed themselves in competition with their own clients to recover against Medtronic over the same allegations. *See* Pet. 5 (admitting that Petitioners learned of Medtronic's supposed wrongdoing while "conducting discovery in a different lawsuit"). The Third Circuit has pointed out the conflict-of-interest problems that arise from "a lawyer arrogating to himself or herself a *qui tam* action based on information learned in the service of a client." *United States ex rel. Stinson, Lyons, Gerlin & Bustamonte, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1161 n.10 (3d Cir. 1991); *see also Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995) (objecting to attorneys usurping from their client the decision whether to file a *qui tam* action).

quantity of the platinum sputter applied to the conductor coils in the 4004/M leads. Medtronic made a documentation change to the specifications to reflect the development of more sensitive measuring technology. If the method of making the product never changed (as counsel for Petitioners conceded at oral argument before the district court, *see* 6th Cir. J.A. 1398-99), then Petitioners' contention that FDA approval for the devices was automatically revoked is factually wrong. (Pet. 4-5). Moreover, as a legal matter, Petitioners' theory that FDA approval was automatically revoked ignores that revocation of FDA approval requires notice and a hearing, followed by formal agency action, none of which occurred here. *See* 21 U.S.C. § 360e(e)(1); 21 C.F.R. § 814.46.

The decision below. In this case, the Sixth Circuit did not reach the merits, as it had in *Kemp*. Rather, it held that the district court lacked jurisdiction due to the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A). The Court found that the allegations in Petitioners' *qui tam* complaint were based upon allegations made against Medtronic in prior products liability litigation. App. 9a.

The Sixth Circuit noted that Medtronic presented filings from a number of products liability lawsuits and FDA administrative reports, but concluded that it needed to consider only one of the products liability actions, *North v. Medtronic*, No. 97-2-16954-2SEA (Wash. Sup. Ct. 1997), to determine that the public disclosure bar was triggered. App. 9a.

North was a products liability action in which the plaintiff alleged that Medtronic "represented to the FDA that it had cured the causes of the past unacceptably high failure rates of the prior leads because it used a platinum sputter coating and stress-relieved insulation for the . . . lead." 6th Cir. J.A. 954. The *North* complaint further alleged, *inter alia*, that (1) Medtronic failed to "rework[] to add appropriate protection" to the leads after performance failures were

observed; (2) there was "fraud surrounding the manufacture" of the pacemaker leads; and (3) the leads "deviated" from design specifications (6th Cir. J.A. 956, 959, 961).

The Sixth Circuit explained that "several prior products liability cases, including *North*[,]" triggered the public disclosure bar, although it mentioned only *North* by name. App. 9a.[2]

Petitioners' statement that the prior products liability suits were "wholly different from Petitioners' federal FCA suit" is inaccurate. (Pet. 7). The Sixth Circuit reviewed the pleadings from *North* and other cases and reached a different conclusion from the Petitioners. App. 10a.

REASONS FOR DENYING THE WRIT

Petitioners now seek this Court's review, claiming (1) that the lower court's interpretation of the statutory phrase "based upon" conflicts with the holdings of a minority of circuits to have addressed the issue, and (2) that its interpretation of the phrase "allegations or transactions" has added to "confusion" in the circuits. (Pet. 9-16). The Petition correctly points out the existence of a circuit split concerning the meaning of "based upon," but overlooks the very narrow category of cases in which the interpretation of that phrase would make any practical difference, overstates the existence of any lower court "confusion" regarding the term "allegations or transactions," and ignores the difficult jurisdictional issue that makes this case an inappropriate vehicle to address the questions posed by the Petition.

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[2] Medtronic also introduced pleadings from, among other prior product liability cases, *Haley v. Medtronic, Inc.*, No. 94-4113 (C.D. Cal. 1994); *Daniel v. Medtronic, Inc.* No. 97-1191 (M.D. Tenn. 1997), and *Redente v. Medtronic, Inc.*, No. 97-649-CIV-T-26C (M.D. Fla. 1997), which made similar allegations that Medtronic used platinum sputtering to cure past lead failures and/or manufactured defective leads or leads that did not conform to FDA specifications.